Remarks

In the Patent Office letter mailed August 25, 2003, a non-final rejection was made of claims 1-61 pending in the application.

In the Office Action, claims 1, 3-19, 21-37, 39-42, 44-53, and 55-61 are rejected under 35 USC 103(a) as being unpatentable over Peabody et al, U.S. Patent 5,643,201, in favor of Polaschegg, U.S. Patent 6,280,632 (referred to as "P"), and Wamsiedler et al, U.S. Patent 5,808,182 (referred to as "W"). Peabody is said to disclose a method and apparatus for operating an automated, continuous, peritoneal dialysis system that comprises dialysate preparation component, a fluid circuit for supplying dialysate to the patient, and a flow of spent dialysate from the patient to drain, a dialysate sterilization component including sterilization filter 53, system controller governing filling and draining, a dialysate storage vessel per claims 32 and 39, the volume of dialysate accumulated being monitored per claims 8, 29, 32+ and 39+, an outflow line segment, and also a system sterilization component.

The claims are said to differ in requiring means to test the sterilization filter in real time. However, W is said to teach such testing of a sterilization filter in a hemodialysis system, as does P. The rejection concludes that it would be obvious to one of ordinary skill in the art to have augmented the Peabody system with means to test the sterilization filter in real time, as taught by W and P, in order to ensure adequate, safe sterilization of the dialysate that contacts the patient to avoid infection, etc., and to ensure adequate delivery of sufficient volumes of dialysate to the patient. The rejection points out in the specification of the respective patents where the alleged teachings are said to be found.

In regard to claims 5, 32+, 42+, and 51, P is said to teach a second area of sterilization filter, as does W.

In regard to claims 4-14, 16-19, 24-26, and 35-37, W and P are said to also teach a sterilization test component using pressurized air applied to the filter being tested and monitoring of subsequent changes in pressure.

Regarding claim 57, isolation and preliminary purging of the filter being tested is said to be taught by at least P.

In regard to claims 20-22 and 59-61, the control of the timing of supplying sterilizing fluid (formaldehyde) by Peabody infers use of a controlled valve.

Regarding claims 30 and 31, Peabody is noted at column 10, lines 11-15, concerning draining and fill cycles.

Regarding claims 28, 33, 34, 40, and 50, use of a discard line segment is said to be taught by P at column 9, line 61.

Regarding claims 41, 52, and 53, the abstract of P is said to teach the testing of a sterilization filter is conducted just prior to dialysate delivery to the dialysis equipment and start of its operation.

Regarding claims 47 and 48, calculating and monitoring of amounts of dialysate being delivered to the patient and of spent dialysate being drained, are said to be taught by Peabody at column 7, lines 49-53, etc.

Claims 2, 20, 38, 43, and 54 are rejected under 35 USC 103(a) as being unpatentable over Peabody U.S. Patent 5,643,201, in view of Wamsiedler U.S. Patent 5,808,181 as applied in claims 1, 23, 32, 39, and 49 above, and further in view of Faict U.S. Patent 5,925,011 (referred to as "F").

Claims 2 requires proportioning of dailysate from multiple sources so as to adjust its osmality, a feature said to be shown by F at column 5, lines 5-11, etc. The rejection states that it would have been obvious to one of ordinary skill in the art to add such proportioning means to the Peabody system, as taught by F, so as to adjust the dialysate to improve the dialysis of waste materials of different types and so as to better ensure safety to the patient by ensuring a pH of the dialysate readily tolerated by organs proximate the peritoneal cavity.

Claims 20, 38, 43 and 54 are said to differ in requiring dialysate delivery systems set up in parallel. Parallel pumping means 12 and 14 are said to be delivered by F. The rejection states that it would have been obvious to have added such parallel delivery system to the Peabody system as taught by F to insure consistent delivery of dialysate to the patient, even in the event of failure of the pump or a clog, etc. occurring in a single delivery system.

Claims 1, 8, 23, 25, 29, and 32, have been amended for syntax and clarity in describing the realtime nature of the dialysate sterilization and the integrity testing of filters as occurring in realtime during dialysis treatment while the patient is connected to the peritoneal dialysis machine, and before delivery of the dialysate to the patient.

Applicants respectfully requests that the rejection of the claims be reconsidered for the reasons set forth below.

Peabody, an inventor in the present application, discloses a peritoneal dialysis system and process. Wamsiedler and Polaschegg disclose conventional hemodialysis machines removing and treating the blood outside the body using an artificial kidney, i.e., a dialyzer filter.

Technology crossovers in the fields of hemodialysis and peritoneal dialysis are not usually known to be made because the fundamental differences in the dialysis processes make the systems virtually inexchangeable. Hemodialysis cleans the blood by removing the blood from the body and circulating the blood through a hemodialysis machine containing a dialyzer, also called an artificial kidney, in an extracorporeal circuit. Blood passes on one side of a membrane in the dialyzer, and dialysis fluid passes on the other side. Waste and excess water pass from the blood through the membrane to the dialysis fluid which is then discarded. The clean blood is returned to the blood stream in the body. In contrast, in peritoneal dialysis the blood is cleaned inside the body, rather than in a machine outside of the body. Sterile dialysate is circulated through the peritoneal cavity on one side of the peritoneal membrane. Waste and excess water pass through the natural peritoneal membrane into the dialysate. Because the dialysis process takes place inside the body, care must be taken in the administration of the fluid so that infection and other problems do not occur.

The prior art references, taken alone or in combination, do not render the rejected claims obvious.

The primary reference, Peabody, discloses sterilizing the dialysis fluid prior to delivery through the inflow circuit connected to the patient. For this purpose, Peabody discloses a reverse osmosis unit A and a sterile dialysis production unit B in a circuit isolated from the inflow circuit. While this provides a rather continuous source of sterilized dialysis fluid, it requires a rather large and expensive machine component not particularly suitable for home use. Peabody discloses an additional micro pore filter in the flow line for sterilization. However, this type of filter does not have a sufficiently

reliable membrane and the membrane is easily broken if subjected to an air integrity test. A system and method for using inline filters with an integrity check conducted in realtime during the peritoneal dialysis treatment while the patient is connected to the system, and prior to patient delivery, is not hinted at by Peabody.

The main secondary references, Wamsiedler and Polaschegg taken from the hemodialysis art, teaches testing sterile filters and/or the dialyzer filter after the dialysis treatment outside the body and before the next treatment. The references do not teach integrity tests of sterilize filters in realtime, during the dialysis treatment while the patient is connected to the machine, nor give any hint for use in a peritoneal dialysis system and process. The references teach testing the integrity of filters after hemodialysis treatment, and before the next treatment, not in realtime during the treatment. Both Wamsiedler and Polaschegg are directed to the problem of providing sterile fluid for substitution in a patient's blood being treated in an external hemodialysis machine. A person skilled in the art would not use these patent references to solve the different problem of the present invention. A person skilled in the dialysis art would choose one of the many dialysis preparation units used in peritoneal dialysis requiring rather large, complex, and expensive sterile fluid preparation components as described in the background part of the description of the present invention as relates to peritoneal dialysis.

In this respect, it is noted that the International Preliminary Examination Report issued on April 4, 2003 in applicant's corresponding PCT application considered similar integrity testing art from the hemodialysis field, and determined the corresponding claims met the criteria for patentability. A copy of the Examination Report accompanies

this Amendment. The report found the claims met the criteria for patentability as set out in PCT Article 33(2)-(3) because the prior art does not teach or fairly suggest a peritoneal dialysis system "comprising a filter integrity test component operatively associated with a sterilization filter assembly for conducting a real time, inline integrity test on the filter assembly to test for a filter failure which would allow contaminants into the dialysate prior to patient delivery and a test sensor to detect a filter failure prior to patient delivery of the dialysate..." (claims 1 and 23). Similar reasons for finding the other claims met the conditions for patentability were stated. The Examination Report was based on U.S. Patent 5,674,404 issued to Kenley et al describing a system and method for testing the integrity of dialyzer filters before reuse in hemodialysis machines. A copy of the Kenley et al reference is enclosed.

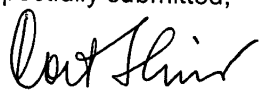
From the above, it can be seen the prior art does not teach or give a hint as to a peritoneal dialysis system comprising a filter integrity test component for conducting an inline integrity test on the filter assembly to test for a filter failure which would allow contaminants into the dialysate in realtime during dialysis treatment while the patient is connected and prior to patient delivery. Wamsiedler and Polaschegg describe systems and methods where the integrity of the sterile filters is tested after the dialysis treatment and before the next treatment to solve different problems.

In accordance with the present invention, substantially unlimited supplies of sterile peritoneal dialysis fluid as needed for home use to effectively and reliably treat a patient using peritoneal dialysis at home are provided without the need for an attendant or costly and complex sterile dialysis preparation units.

Not only do the independent claims meet the conditions for patentability for the reasons given above, but several aspects of the invention set forth in the dependent claims are not disclosed or hinted at by the prior art. For example, the way the sterilization filter assembly and filter testing component and control valve arrangements are connected in the fluid flow circuits necessary for sterilization and filter testing in realtime during treatment as set forth in claims 4, 5, 6, and 24 are not shown. There is no delivery vessel connected to the outlet of any sterilization filter in the prior art references for accumulating the dialysate after it has passed through a sterilization filter assembly and storing the dialysate while the integrity test is performed on the filter assembly before the dialysate is delivered to the patient in the peritoneal dialysis is not shown Among other claims, these aspects are pointed out in claims 8, 11, 18, 29, 32, 35, 36, 39, 40, 50, and new dependent claims 62-64. The use of a fluid circuit sterilization component as set forth in claims 1, 21, 22, for sterilizing the entire fluid flow circuit and components in the event that a filter integrity test has failed in realtime during the dialysis treatment is not taught in the prior art.

For the above reasons, applicant respectfully requests that the rejection be reconsidered, and claims 1 through 64, including new dependent claims 62–64, be allowed. Such action is respectfully requested in due course of Patent Office business.

Respectfully submitted,



Cort Flint, Registration No. 27,260
McNAIR LAW FIRM, P.A.
P.O. Box 10827
Greenville, SC 29603-0827
Telephone: (864) 232-4261

Attorney for the Applicant

GREENVILLE 181326v1

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: CORT FLINT
MCNAIR LAW FIRM, P.A.
P.O. BOX 10827
GREENVILLE, SOUTH CAROLINA 29603

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

	Date of Mailing *(day/month/year)* 04 APR 2003
Applicant's or agent's file reference PEA13PCT	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US02/04373	14 FEBRUARY 2002	16 FEBRUARY 2001

Applicant
PIEDMONT RENAL CLINICS, P.A.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

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For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	SUN UK KIM Jean Proctor Paralegal Specialist
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0661

Form PCT/IPEA/416 (July 1992)★

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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MCNAIR LAW FIRM, P.A.
P.O. BOX 10827
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Facsimile No. (703) 305-3230	Telephone No. (703) 308-0661

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PEA13PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US02/04373	International filing date *(day/month/year)* 14 FEBRUARY 2002	Priority date *(day/month/year)* 16 FEBRUARY 2001
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant PIEDMONT RENAL CLINICS, P.A.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☒ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21 AUGUST 2002	12 MARCH 2003
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer SUN UK KIM Jean Proctor Paralegal Specialist Telephone No. (703) 308-0661

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/04373

I. Basis of the rep rt

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages (See Attached) , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the claims:
pages (See Attached) , as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the drawings:
pages (See Attached) , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the sequence listing part of the description:
pages (See Attached) , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/04373

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- [ ] restricted the claims.
- [X] paid additional fees.
- [ ] paid additional fees under protest.
- [ ] neither restricted nor paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- [ ] complied with.
- [X] not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- [X] all parts.
- [ ] the parts relating to claims Nos. _.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/04373

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-69	YES
	Claims	NONE	NO
Inventive Step (IS)	Claims	1-69	YES
	Claims	NONE	NO
Industrial Applicability (IA)	Claims	1-69	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-69 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the peritoneal dialysis system of claims 1 and 23 comprising a filter integrity test component operatively associated with a sterilization filter assembly for conducting a realtime, in-line integrity test on the filter assembly to test for a filter failure condition which would allow contaminants into the dialysate prior to patient delivery, a test sensor in communication with the integrity testing component for detecting the failure condition, the peritoneal dialysis system of claim 32 comprising a filter test component operatively associated with primary and secondary sterilization filter assemblies for conducting a realtime, in-line integrity test on the filter assemblies to test for a filter failure condition which would allow contaminants into the dialysate prior to patient delivery and the peritoneal dialysis process of claims 39 and 44 comprising the steps of subjecting an in-line filter assembly to a filter integrity test to test for a filter failure that would allow contaminants into the dialysate prior to patient delivery and delivering the sterile dialysate from a delivery vessel to patient's peritoneal cavity after the filter integrity test is passed and the method of claim 55 comprising the steps of passing dialysate through at least one in-line sterilization filter assembly connected in an inflow line to the patient in realtime prior to delivery to patient and testing the sterilization filter assembly in realtime for a filter failure condition prior to delivering dialysate to the peritoneal cavity of the patient. Claims 2-22 depend on the novel and nonobvious claim 1. Claims 2-22 depend on the novel and nonobvious claim 1. Claims 24-31 depend on the novel and nonobvious claim 23. Claims 33-38 depend on the novel and nonobvious claim 32. Claims 40-43 depend on the novel and nonobvious claim 39. Claims 45-54 depend on the novel and nonobvious claim 44. Claims 56-69 depend on the novel and nonobvious claim 55.

Claims 1-69 have industrial applicability as defined by PCT Article 33(4) because the claimed subject matter can be made and/or used in peritoneal dialysis industry.

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): A61M 1/14, 1/28; B01D 61/24, 61/26, 61/28, 61/32 and US Cl.: 210/85, 87, 97, 106, 321.71, 645, 646, 739; 604/28, 29, 30

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
page(s) 1-33, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
page(s) 34, 36-42, 44-52, as originally filed.
page(s) NONE, as amended under Article 19.
page(s) NONE, filed with the demand.
and additional amendments:
Pages 35 and 43, filed with the letter of 26 February 2003.

This report has been drawn on the basis of the drawings,
page(s) 1-12, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the sequence listing part of the description:
page(s) NONE, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

As applicant was previously notified this International Preliminary Examining Authority has found plural inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-22, drawn to a peritoneal dialysis system comprising a proportioning component for adjusting the osmolarity of the dialysate supply, an inflow sensor in communication with an inflow line, an outflow sensor in communication with an outflow line and a control system for controlling the inflow and outflow delivery in response to the inflow and outflow signals during the fill and drain cycles.
Group II, claims 23-31 and 55-69, drawn to a peritoneal dialysis system comprising in-line sterilization filter assembly including an inlet port connected in an inflow line segment for receiving unsterilized dialysate, a sterilization filter medium through which the dialysate passes for producing sterilized dialysate and an outlet port connected in the inflow line segment through which sterilized dialysate flows to the patient.
Group III, claims 32-54, drawn to a peritoneal dialysis system comprising a sterilization unit including a primary in-line sterilization filter assembly, a secondary in-line sterilization filter assembly, a delivery vessel and secondary filter assembly.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: All of the groupings are directed to a method or apparatus for peritoneal dialysis, but each group has a different special technical feature not shared by the remaining groups. Group I is directed to an apparatus which has the special technical feature of a proportioning component for adjusting the osmolarity of the dialysate supply, an inflow sensor in communication with an inflow line, an outflow sensor in communication with an outflow line and a control system for controlling the inflow and outflow delivery in response to the inflow and outflow signals during the fill and drain cycles not shared by any of the remaining groups. Group II is directed to an apparatus which has the special technical feature of in-line sterilization filter assembly including an inlet port connected in an inflow line segment for receiving unsterilized dialysate, a sterilization filter medium through which the dialysate passes for producing sterilized dialysate and an outlet port connected in the inflow line segment through which sterilized dialysate flows to the patient not shared by any of the remaining groups. Group III is directed to an apparatus which has the special technical feature of a sterilization unit including a primary in-line sterilization filter assembly, a secondary in-line sterilization filter assembly, a delivery vessel and secondary filter assembly not shared by any of the remaining groups.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

---------- NEW CITATIONS ----------
NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: CORT FLINT
MCNAIR LAW FIRM, P.A.
P.O. BOX 10827
GREENVILLE, SOUTH CAROLINA 29603

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Applicant's or agent's file reference PEA13PCT	Date of Mailing *(day/month/year)* 04 APR 2003
	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US02/04373	14 FEBRUARY 2002	16 FEBRUARY 2001

Applicant
PIEDMONT RENAL CLINICS, P.A.

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Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	SUN UK KIM Jean Proctor Paralegal Specialist
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0661

Form PCT/IPEA/416 (July 1992)★